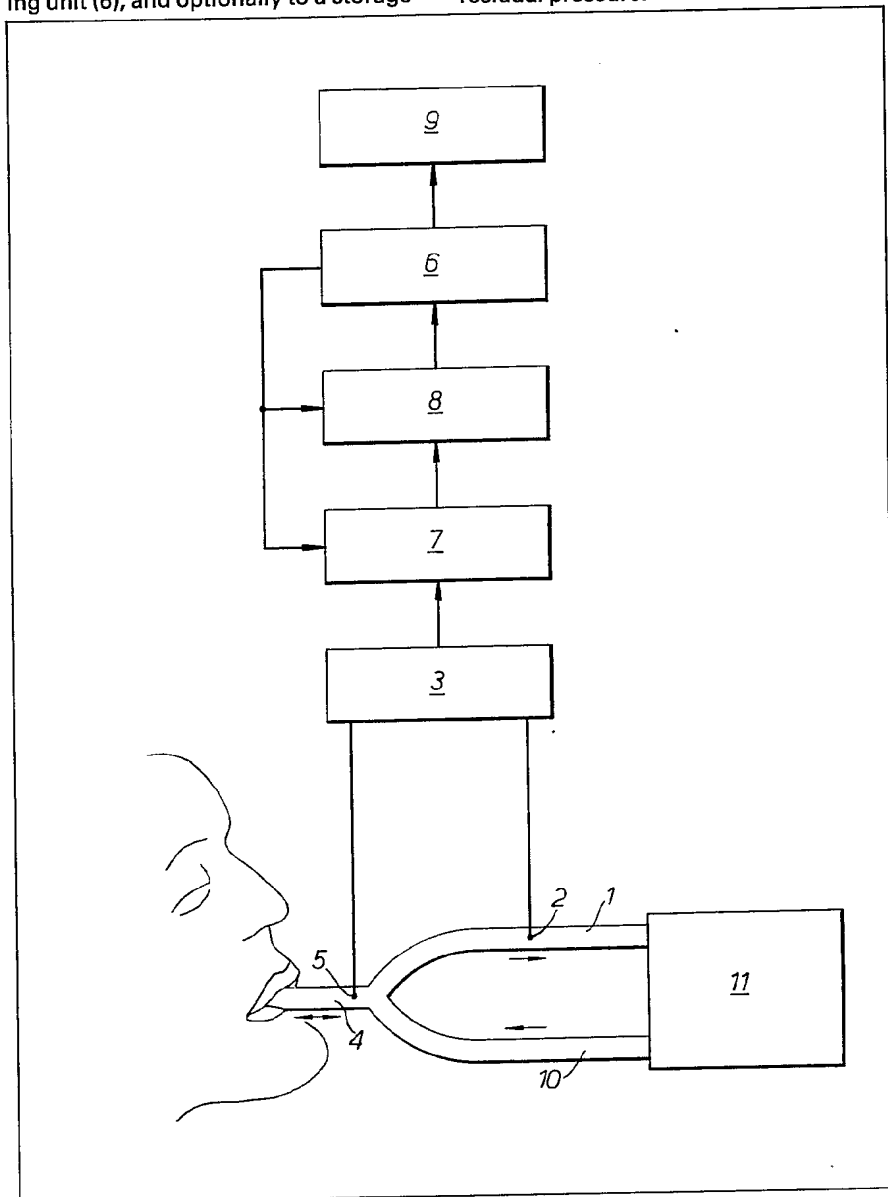


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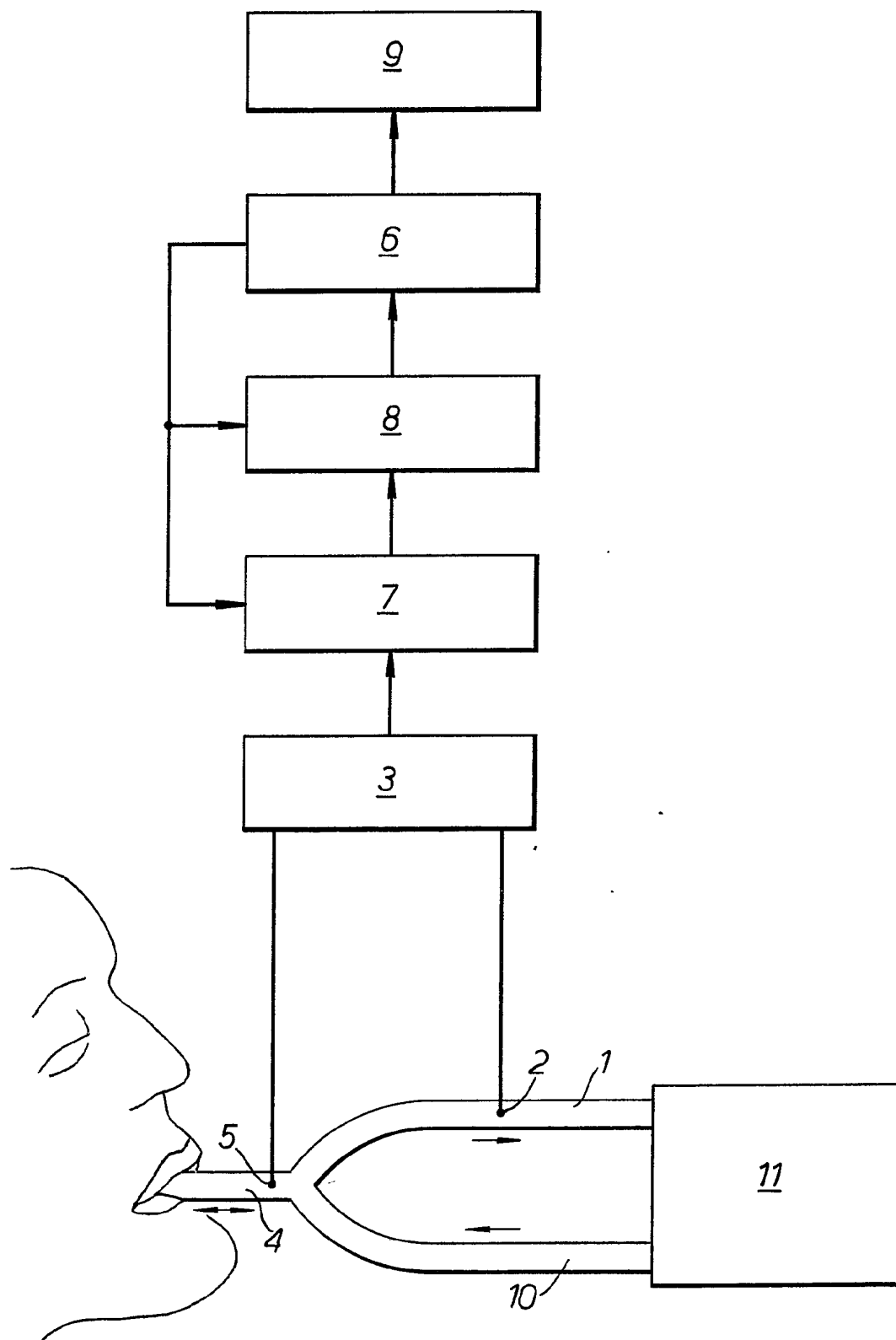
(54) **Determining at least two parameters of a patient's respiratory system**

(57) The outputs of a pressure sensor (5), a flow sensor (2) and a volume determining device (3), which may determine the volume by integrating the flow rate with respect to time, are connected to a monitoring unit (7) which in turn is connected to a calculating unit (6), and optionally to a storage

unit (8). During each respiratory cycle the monitoring unit (7) supplies the calculating unit (6) with at least two sets of sensed values of the pressure, the flow rate and the volume from which the calculating unit (6) then calculates the required parameters of the respiratory system. These parameters could be, for example, a linear component of the airway resistance, a quadratic component of the airway resistance, a compliance of the lungs, and an alveolar residual pressure.



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## SPECIFICATION

**Apparatus for, and method of, determining at least two parameters of a patient's respiratory system**

- 5 This invention relates to an apparatus for, and a method of, determining at least two parameters of a patient's respiratory system. 5
- These parameters could be, for example, a linear component of the airway resistance  $R_1$ , a quadratic component of the airway resistance  $R_2$ , the compliance  $C$  and the alveolar residual pressure  $P_0$ . These measured parameters could be supplied as input signals to a ventilating apparatus, and could be determined from measurements from a pressure sensor, a flow meter in a respiratory air passage, and a corresponding volume signal provided by a time-controlled integrator which integrates the flow signal. 10
- For individual patients whose respiratory system is to be monitored, in particular patients ventilated by a ventilating apparatus, it is necessary to determine continuously and rapidly pneumatic parameters of the patient's respiratory system.
- 15 For example, German Offenlegungsschrift 25 13 676 specifies an electronic apparatus for measuring and indicating automatically the flow resistance  $R$  of the air in the bronchial passages, and the elasticity  $E$  of the pulmonary tissue on the basis of measured values of the respiratory air flow and the change in the endothoracic pressure. 15
- German Offenlegungsschrift 27 19 900 discloses a respiration-analysis apparatus in which the respiratory gas flow can be measured by time integration from differential pressure signals and additional pneumatic parameters, such as absolute tracheal and bronchial pressure. 20
- German Offenlegungsschriften 24 13 988 and 25 22 774 disclose methods of exploring the intrathoracic breathing mechanism, and consequently of determining pneumatic lung parameters.
- Finally, German Auslegeschrift 19 33 472 discloses a ventilating or anaesthesia ventilating apparatus wherein the pneumatic lung parameters are determined from a curve of measured instantaneous values. 25
- German Offenlegungsschrift 23 37 061 discloses another apparatus for measuring a respiratory volume in conjunction with a respiratory pressure transducer, which trigger a controlled indicating and/or alarm arrangement which responds to a variable which is dependent on the ratio of the respiratory pressure to the respiratory volume.
- 30 Due to the great variation in the measured values in the respiratory air flow, in the known apparatus, the pneumatic lung parameters calculated and indicated respectively are too inaccurate for many monitoring purposes. 30
- What is required is an apparatus in which it is possible to determine the desired pneumatic lung parameters rapidly and with a high degree of accuracy.
- 35 According to the present invention there is provided an apparatus suitable for use in determining at least two required parameters of a human or animal respiratory system, the apparatus comprising: a pressure sensor for sensing the pressure in a respiratory passage through which in use inhalation and/or exhalation gas passes; a flow sensor for sensing in use the flow rate of inhalation and/or exhalation gas; a volume sensor for sensing the volume of gas which is inhaled and/or exhaled; a monitoring unit to which the pressure sensor, the flow sensor and the volume sensor are connected; and a calculating unit connected to the monitoring unit; the arrangement being such that, during each respiratory cycle, the monitoring unit supplies the calculating unit with at least two sets of sensed values of said pressure, said flow rate and said volume and the calculating unit calculates the required parameters of the respiratory system from the sets of sensed values. 40
- 45 Preferably, the monitoring unit stores the monitored sets of values in a storage unit, which is capable of being periodically cleared, and which is connected to the calculating unit. 45
- The volume sensor can comprise a time-controlled integrator connected to the flow sensor, which time-controlled integrator integrates the flow rate to obtain the volume of gas which is inhaled and/or exhaled.
- 50 The calculating unit can calculate the required parameters from linear equations. 50
- The apparatus can determine two or more of the following parameters of a respiratory system: a linear component of the airway resistance; a quadratic component of the airway resistance; a compliance of the lungs; and a residual pressure in the alveoli.
- The apparatus can include an indicating and/or control unit which displays the parameters determined by the calculating unit. 55
- The apparatus can also include a ventilator controlled by an output of the calculating unit. The output of the calculating unit can be connected to the ventilator by the indicating and/or control unit.
- The apparatus can be that, in which at least 50 sets of values are monitored by the monitoring unit during each respiratory cycle.
- 60 The monitoring unit can monitor the sets of values either in the exhalation phase or in the inhalation phase of each respiratory cycle. 60
- The calculating unit can comprise a microprocessor.
- The monitoring unit can be connected to the pressure sensor and the flow sensor via a measured value unit, which includes the volume sensor.
- 65 In practice in an embodiment of an apparatus according to the present invention, signals generated by 65

pressure sensor and the flow sensor are measured in an electronic circuit, and the volume is determined by integration from the flow measurement or by direct measurement. The variables forming a set of monitored or sensed values, a monitored value triplet, are available as electrical voltages and are monitored accordingly.

- 5 In order to coordinate the monitoring or measurement of sets of values with respect to the inhalation or exhalation phase of a respiratory cycle, the monitoring unit advantageously checks the flow gradient or rate of change of flow. If, for a time, the flow equals 0 and suddenly becomes >0, then it is assumed that exhalation has commenced, and subsequently in the exhalation phase the necessary number, generally as high as possible, of the sets of monitored values  $p$ ,  $\dot{V}$ ,  $\dot{V}$  are stored, values of the rate of change of the flow which will be rising in magnitude also having to be included. These stored values serve to identify and distinguish the inhalation phase from the exhalation phase. The maximum flow rate in the exhalation phase typically occurs approximately 50 ms after exhalation commences. The monitoring period, that is, the time span during which sets of monitored values are stored, must at least equal the time constants of the lungs. If, for example, the values for  $R_1$ ,  $R_2$ ,  $C$  and  $P_0$  are to be determined, then the linear equation system

$$P_i + R_1 \cdot \dot{V}_i + R_2 \cdot \ddot{V}_i - \frac{1}{C} (V_0 - V_i) = P_0$$

- 20  $i = 1, 2, 3, 4$

can be taken as a basis, wherein the equation coefficients are determined from four sets of monitored values, each set comprising a triplet of values ( $p$ ,  $\dot{V}$  and  $V$ ). The linear equation system is resolvable unless in each case two of the variables  $P$ ,  $\dot{V}$  and  $V$  are linearly dependent.

- 25 With this direct determination all measuring errors are processed also, and, in addition to this, calculation fails if one of the three variables  $P$ ,  $\dot{V}$  and  $V$  is constant. If, however, a plurality, more particularly a multiplicity, of sets of monitored values is stored, then the linear equation system specified above can be represented as a minimum condition of the square of errors:

- 30 
$$\sum_{i=1}^n [P_i + R_1 \cdot \dot{V}_i + R_2 \cdot \ddot{V}_i - \frac{1}{C} (V_0 - V_i) - P_0]^2 \rightarrow \text{Min}$$

- 35 where  $V_i = \int_{t=0}^{t=t_i} \dot{V}(t) \cdot dt$

$i$  = current number of the scanned value

- 40  $n$  = number of the sets of monitored values ( $p$ ,  $\dot{V}$ ,  $V$ ). Here,

$\dot{V}$  is the instantaneous value of the flow

$V_0$  is the volume of the inflated lungs at the end of inhalation

$P$  is the instantaneous value of the pressure before the mouth

- 45  $P_0$  is the alveolar residual pressure

$R_1$  is a linear component of the airway resistance

$R_2$  is a quadratic component of the airway resistance

$C$  is the compliance of the lungs, that is, the reciprocal value of the elasticity of the lungs.

- After storing the required number of sets of monitored values, the values for  $R_1$ ,  $R_2$ ,  $C$  and  $P_0$ , which should be optimum in terms of measuring techniques, are calculated by the specified equation system from  $n$  stored measured value-triplets, and indicated. The apparatus can indicate after each breath the values of  $R_1$ ,  $R_2$ ,  $C$  and  $P_0$  which are value for that breath.

- The flow is preferably measured in the exhalation branch, when separate inhalation and exhalation branch ducts are provided. However, measurement is also possible in the inhalation branch or in a respiratory air passage common to both inhalation and exhalation.

- The apparatus is also capable of functioning if the patient is not connected to a ventilating apparatus, and inhales and exhales simply by way of a measuring tube, if, through corresponding valve control, care is taken that when exhalation commences,  $P > 0$  and  $p$  drops while  $|\dot{V}|$  rises. The apparatus is also applicable if the patient is in a spontaneous or IMV or SIMV ventilated state, and also in the case of PEEP.

- 60 In simpler embodiments of the apparatus, if necessary, only two pneumatic lung parameters, preferably the linear component of the airway resistance  $R_1$ , and the compliance  $C$ , omitting the quadratic component of the airway resistance  $R_2$  and the alveolar residual pressure  $P_0$ , are determined.

- Through measurement,  $p$ ,  $\dot{V}$  or  $V$  are influenced neither during the inhalation nor during the exhalation phase. Furthermore, it is not necessary to reach an end exhalation or an end inhalation plateau for  $P$ ,  $\dot{V}$  or  $V$ ; the presence of a linear exhalation resistance likewise does not constitute a pre-requisite for the applicability

of the apparatus, which can also be used for non-linear exhalation resistances.

The accuracy of the measuring result increases with the number of the sets of monitored values which are scanned or monitored. This number should be increased as the measuring errors in the individual determination variables  $p$ ,  $\dot{V}$  and  $V$  increase.

5 The present invention also provides a method of determining at least two required parameters of a human or animal respiratory system, the method comprising: monitoring with a monitoring unit the pressure of respiratory gas, in a respiratory passage through which inhalation and/or exhalation gas flows, the flow rate of the respiratory gas and the volume of respiratory gas which has been inhaled and/or exhaled; during each respiratory cycle, supplying a calculating unit with at least two sets of monitored values of said pressure, said flow rate and said volume; and calculating the required parameters of the respiratory system for the sets of monitored values. 10

Preferably two or more of the following parameters of the respiratory system are determined: a linear component of the airway resistance; a quadratic component of the airway resistance; a compliance of the lungs; and a residual pressure in the alveoli.

15 Conveniently, the volume of respiratory gas which has been inhaled and exhaled is obtained by integrating the flow rate of the respiratory gas with respect to time. 15

The method preferably also includes a step of determining whether each set of monitored values is obtained during an inhalation phase or an exhalation phase, by monitoring the rate of change of a variable of the respiratory cycle.

20 Preferably, during each respiratory cycle, the sets of monitored values are stored in a storage device, and the sets of monitored values are supplied from the storage unit to the calculating unit. 20

Preferably, after each respiratory cycle, the storage device is cleared so that new sets of monitored values can be stored therein.

25 Preferably, the required parameters of the respiratory system are calculated from the sets of monitored values using a least-squares technique. 25

The method of the present invention can be carried out in an apparatus as defined above.

For a better understanding of the present invention and to show more clearly how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawing which shows a block diagram of an apparatus according to the present invention.

30 A flow sensor 2 is disposed in an exhalation branch duct 1 and is connected to a measured value unit 3. The flow sensor 2 senses the flow rate in the exhalation branch duct 1 and provides the measured value unit 3 with a signal representative of the flow variable  $\dot{V}$ , and this signal is integrated in the measured value unit 3 to give the volume variable  $V$ . 30

35 In a common respiratory air passage 4 a pressure sensor 5 is provided with senses the pressure therein. Its output variable likewise being fed to the measured value unit 3 and being determined as  $p$ . Therefore, in the measured value unit 3 the variables  $p$ ,  $\dot{V}$  and  $V$  are always present. Monitoring takes place through signals from a calculating unit 6 provided with a microprocessor, which, by monitoring the magnitude of the flow rate also determines when the desired measuring phase (inhalation or exhalation) commences. 35

40 The sets of monitored values, triplets of values, monitored by the monitoring unit 7, are stored in a storage unit 8. The maximum number of sets of monitored values which can be stored in the storage unit 8 is 250, the storage unit 8 being capable of being cleared. At the end of each measuring phase the sets of monitored values are transferred from the storage unit 8 to the calculating unit 6, and there, on the basis of linear equation systems according to a least squares method, optimum values of the required pneumatic lung parameters  $R_1$ ,  $R_2$ ,  $C$  and  $P_0$  to be determined are calculated, and are indicated by an indicating unit 9. 40

45 The exhalation branch 1 and an inhalation branch 10 of the common respiratory air passage 4 are connected in the present case to a ventilating apparatus 11. 45

#### CLAIMS

50 1. An apparatus suitable for use in determining at least two required parameters of a human or animal respiratory system, the apparatus comprising: a pressure sensor for sensing the pressure in a respiratory passage through which in use inhalation and/or exhalation gas passes; a flow sensor for sensing in use the flow rate of inhalation and/or exhalation gas; a volume sensor for sensing the volume of gas which is inhaled and/or exhaled; a monitoring unit to which the pressure sensor, the flow sensor and the volume sensor are 55 connected; and a calculating unit connected to the monitoring unit; the arrangement being such that, during each respiratory cycle, the monitoring unit supplies the calculating unit with at least two sets of sensed values of said pressure, said flow rate and said volume and the calculating unit calculates the required parameters of the respiratory system from the sets of sensed values. 55

2. An apparatus as claimed in claim 1, wherein the monitoring unit stores the monitored sets of values in a storage unit, which is capable of being periodically cleared, and which is connected to the calculating unit. 60

3. An apparatus as claimed in claim 1 or 2, in which the volume sensor comprises a time-controlled integrator connected to the flow sensor, which time-controlled integrator integrates the flow rate to obtain the volume of gas which is inhaled and/or exhaled.

4. An apparatus as claimed in any preceding claim, wherein the calculating unit calculates the required parameters from linear equations. 65

5. An apparatus as claimed in any preceding claim, which determines two or more of the following parameters of a respiratory system: a linear component of the airway resistance; a quadratic component of the airway resistance; a compliance of the lungs; and a residual pressure in the alveoli.
6. An apparatus as claimed in any preceding claim, which includes an indicating and/or control unit
- 5 which displays the parameters determined by the calculating unit. 5
7. An apparatus as claimed in any preceding claim which includes a ventilator controlled by an output of the calculating unit.
8. An apparatus as claimed in claim 7, when appendant to claim 6, wherein the output of the calculating unit is connected to the ventilator by the indicating and/or control unit.
- 10 9. An apparatus as claimed in any preceding claim, in which at least 50 sets of values are monitored by the monitoring unit during each respiratory cycle. 10
10. An apparatus as claimed in any preceding claim, in which the monitoring unit monitors the sets of values either in the exhalation phase or in the inhalation phase of each respiratory cycle.
11. An apparatus as claimed in any preceding claim, in which the calculating unit comprises a
- 15 microprocessor. 15
12. An apparatus as claimed in any preceding claim, in which the monitoring unit is connected to the pressure sensor and the flow sensor via a measured value unit, which includes the volume sensor.
13. An apparatus substantially as hereinbefore described with reference to, and as shown in, the accompanying drawing.
- 20 14. A method of determining at least two required parameters of a human or animal respiratory system, the method comprising: monitoring with a monitoring unit the pressure of respiratory gas, in a respiratory passage through which inhalation and/or exhalation gas flows, the flow rate of the respiratory gas and the volume of respiratory gas which has been inhaled and/or exhaled; during each respiratory cycle, supplying a calculating unit with at least two sets of monitored values of said pressure, said flow rate and said volume; 20
- 25 and calculating the required parameters of the respiratory system for the sets of monitored values. 25
15. A method as claimed in claim 14, wherein two or more of the following parameters of the respiratory system are determined: a linear component of the airway resistance; a quadratic component of the airway resistance; a compliance of the lungs; and a residual pressure in the alveoli.
16. A method as claimed in claim 14 or 15, wherein the volume of respiratory gas which has been inhaled and exhaled is obtained by integrating the flow rate of the respiratory gas with respect to time. 30
- 30 17. A method as claimed in claim 14, 15 or 16, which also includes a step of determining whether each set of monitored values is obtained during an inhalation phase or an exhalation phase, by monitoring the rate of change of a variable of the respiratory cycle.
18. A method as claimed in claim 14, 15, 16 or 17 wherein, during each respiratory cycle, the sets of monitored values are stored in a storage device, and the sets of monitored values are supplied from the storage unit to the calculating unit. 35
- 35 19. A method as claimed in claim 18, wherein after each respiratory cycle, the storage device is cleared so that new sets of monitored values can be stored therein.
20. A method as claimed in any one of claims 14 to 19, wherein the required parameters of the
- 40 respiratory system are calculated from the sets of monitored values using a least-squares technique. 40
21. A method as claimed in any one of claims 14 to 20 when carried out in an apparatus as claimed in any one of claims 1 to 13.